DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127-2601

Telephone: 504-253-4519
Fax: 504-253-4520

November 9, 2001

WARNING LETTER NO. 2002-NOL-08

FEDERAL EXPRESS
NEXT DAY DELIVERY

Mr. Mike Walsh, CEO
LifeGas, Ltd.
6659 Peachtree Industrial Boulevard
Suite AA
Norcross, Georgia 30092

Dear Mr. Walsh:

During the October 17 – 18, 2001, inspection of your facility, located at 5712 Heebe Street, Harahan, Louisiana, our investigator documented deviations from the Current Good Manufacturing Practice regulations. These deviations cause your drug product, Oxygen USP, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) in that the controls used for the manufacturing, processing, packing or holding of this product are not in conformance with Current Good Manufacturing Practice Regulations, Title 21, *Code of Federal Regulations*, Part 211.

Specific observations made during the inspection include:

1. You failed to witness the testing of incoming liquid Oxygen USP at your supplier for purity and strength prior to filling the cryogenic home units.

2. You failed to assay the incoming bulk, liquid Oxygen USP for purity and strength.

3. You failed to train your employees on the bulk, liquid oxygen filling operations, analyzing equipment calibration procedures, and liquid Oxygen USP testing procedures performed by your firm's supplier.

4. You failed to document the pre-fill and post-fill weights of each cryogenic vessel and the performance of an odor test on each cryogenic vessel in accordance with your Standard Operating Procedures.

5. You have not installed any oxygen analyzing equipment; however, your batch production records show that the purity of the Oxygen USP as "NA" yet the same records state that the product was analyzed and identifies the analyst through his signature.

The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to assure adherence with each requirement of the Current Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to properly correct them may result in regulatory action without further notice. This may include seizure and/or injunction.

We are aware that at the close of the inspection [redacted] Branch Manager, made a verbal commitment to correct the observed deficiencies. In addition, we received a written response from [redacted] Director of Safety and Compliance, dated October 22, 2001. We will evaluate this response and respond in a separate letter. However, it is necessary that you notify this office in writing, within 15 days of the receipt of this letter, of the steps that you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Mark W. Rivero, Compliance Officer, U.S. Food and Drug Administration, at the above address. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Mr. Rivero at telephone number (504) 253-4519.

Sincerely,

Carl E. Draper

Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA 483

cc: [redacted] Branch Manager
LifeGas, Ltd.
5712 Heebe Street
Harahan, Louisiana 70130